



Department of Energy
Office of Civilian Radioactive Waste Management
Yucca Mountain Site Characterization Office
P.O. Box 98608
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JAN 17 1995

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Albuquerque, NM 87185

EVALUATION OF AMENDED RESPONSE TO CORRECTIVE ACTION REQUEST
(CAR) YM-94-099 RESULTING FROM YUCCA MOUNTAIN QUALITY ASSURANCE
DIVISION (YMQAD) AUDIT YMP-94-099 OF SANDIA NATIONAL LABORATORIES
(SCPB: N/A)

The YMQAD staff has evaluated the amended response to CAR YM-94-099. The amended response has been determined to be satisfactory. Verification of completion of the corrective action will be performed after the effective date provided. Any extension to this date must be requested in writing, with appropriate justification, prior to the date. Please send a copy of extension requests to Deborah Sult, YMQAD/QATSS, 101 Convention Center Drive, Suite 640, Las Vegas, Nevada 89109.

If you have any questions, please contact either Robert B. Constable at (702) 794-7945 or James Blaylock at (702) 794-7913.

YMQAD:RBC-1739

Richard E. Spence, Director
Yucca Mountain Quality Assurance Division

Enclosure:
CAR YM-94-099

cc w/encl:
~~J. G. Spraul~~, NRC, Washington, DC
S. W. Zimmerman, NWPO, Carson City, NV

cc w/o encl:
W. L. Belke, NRC, Las Vegas, NV
D. G. Sult, YMQAD/QATSS, Las Vegas, NV

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CORRECTIVE ACTION REQUEST

1 Controlling Document QAIP 20-02, Paragraph 4.1		2 Related Report No. YMP-94-09	
3 Responsible Organization SNL		4 Discussed With D. Kessel/J. Potts	
5 Requirement: Scientific Notebooks shall be reviewed by a competent independent individual to verify there is sufficient detail to retrace the investigation and confirm the results, if feasible, or report the investigation and achieve comparable results without recourse to the original investigator.			
6 Adverse Condition: Contrary to the requirement above: 1. WA-0071 SN, "Rock Mass Quantitative Index Derived from NRG Core Data," Section 2, the methodology for determining the parameter Jc in the RMR rock mass classification process was not traceable. 2. Documentation is insufficient in the WA-0116 SN, "Alcove Blast Project," Section 4 (Video Logs of Boreholes), and Section 6 (Analysis); missing titles of name, column headings, data units, acronyms, and insufficient description of methodology. 3. Laboratory Notebook: YMSCP Fracture Properties Experiments, WA-0091, Task 4 (Fracture Surface Testing in Support of ESF Design), NRG-4-537.8, Test ID YMP No. 4. Test control parameters delta and zero were not defined.			
9 Does a Significant Condition Adverse to Quality exist? Yes <u> </u> No <u>X</u> If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E		10 Does a stop work condition exist? Yes <u> </u> No <u>X</u> ; If Yes - Attach copy of SWO If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	
13 Response Due Date: 20 Working Days From Issuance			
11 Required Actions: <input checked="" type="checkbox"/> Remedial <input checked="" type="checkbox"/> Extent of Deficiency <input checked="" type="checkbox"/> Preclude Recurrence <input checked="" type="checkbox"/> Root Cause Determination			
12 Recommended Actions:			
7 Initiator <u>James Blaylock</u> James Blaylock		14 Issuance Approved by: <u>[Signature]</u> QADD <u>[Signature]</u> Date <u>9.12.94</u>	
15 Response Accepted QAR _____ Date _____		16 Response Accepted QADD _____ Date _____	
17 Amended Response Accepted QAR <u>James Blaylock</u> Date <u>1/12/95</u>		18 Amended Response Accepted QADD <u>[Signature]</u> Date <u>1.17.95</u>	
19 Corrective Actions Verified QAR _____ Date _____		20 Closure Approved by: QADD _____ Date _____	

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CORRECTIVE ACTION REQUEST (CONTINUATION PAGE)

1. Corrective Action for CAR No, YM-94-099, Adverse Condition #2

A. Remedial Action

Additional documentation will be added to WA-0116 SN "Alcove Blast Project", Section 4 and Section 6. Missing titles, column headings, data units, acronyms, and sufficient description of methodology will be added.

John Pott will complete this action by November 30, 1994.

B. Extent of Deficiency.

A review of other SNs submitted under WA-0116 determined that the missing documentation was limited to the SN "Alcove Blast Project."

There was no adverse impact to the quality of the data obtained under this SN and when the additional documentation is added, no conditions adverse to quality will exist.

C. Root Cause Determination.

The SN was submitted with an insufficiently thorough review. This SN was among the first submitted by the PI.

D. Corrective Action to Preclude Recurrence.

The task leader (John Pott) will provide training in accordance with QAIP 2-5 to those involved in generating and reviewing the Sns for WA-0116 by November 30, 1994.

Responsible Individual:


John Pott

10-10-94

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099 10/12/94
Corrective Action Response for CAR # YM-94-09, Adverse Condition # 1

Remedial Action

An addendum to the Scientific Notebook WA-0071 Rock Mass Quality Index Derived From NRG Core Data has been added. The addendum documents the methodology for the calculation of the parameter Jc.

Extent of the Deficiency

This was an isolated occurrence. All other Rock Mass Quality calculations were judged to be adequately documented in the SN.

A review of other SNs developed under WA-0071 determined that the missing documentation was limited to one SN.


There was no adverse impact to the quality of the data obtained under this SN and with the additional documentation no conditions adverse to quality exist.

Root Cause Determination

The level of detail in the notebook was not sufficient. The guidance provided by the Task Leader for the level of detail required to document analyses was inadequate.

Corrective Action to Prevent Recurrence

The task leader (Dave Kessel) will provide training in accordance with QAIP 2-5 to those involved in generating scientific notebooks for WBS 1.2.3.2.6.2. The training will be completed by November 30, 1994.


for L.E. Shephard 10/12/94

10/13/94 LTR. SHEPHARD TO SPENCE

1. CORRECTIVE ACTION RESPONSE for Adverse Condition #3**(a) Remedial Action:**

None is required.

(b) Extent of Deficiency:

The parameters, delta and zero, are common to every data acquisition set-up file in this series of experiments. There is a general reference to the SAND document (SAND93-0256, entitled '*Event Triggered Data Acquisition in the Rock Mechanics Laboratory*') that describes the data acquisition software in the front of the cited scientific notebook. This SAND Report defines all common parameters in the set-up files. Therefore, there is no deficiency.

(c) Preclude Recurrence:

Not Applicable

(d) Root Cause:

Not Applicable

2. RESPONSIBLE INDIVIDUAL

Ronald H. Price is responsible for this corrective action response.

3. SIGNATURE of RESPONSIBLE INDIVIDUAL

Ronald H. Price
Signature

10/11/94
Date

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EVALUATION OF THE RESPONSE FOR CAR YM-94-099

The response to CAR YM-94-099 has been evaluated and rejected. The response to the CAR is very shallow in that the actions requested included extent of deficiency, root cause determination, and corrective action to prevent recurrence are not sufficiently comprehensive.

The response addressed only those scientific notebooks identified in the CAR, whereas the extent of deficiency should entail a broader, more comprehensive consideration of notebooks generated by Sandia National Laboratories (SNL) principal investigators (PI's). Likewise, the root cause makes no commitment to address the level of detail via procedural changes but relies on "guidance" to be provided by Task Leaders. This will not result in consistent scientific notebooks being generated by SNL PI's. Likewise, the response references a "review" that found all examples to be either isolated occurrences or non deficiencies. There is nothing to indicate what the criteria for this review was, nor any confidence that the reviews by the various PI's was meaningful or thoughtful. Finally, with the flaws identified above, the corrective action to prevent recurrence may not be adequate or sufficient due to the shortcomings described above.

James Blaylock
James Blaylock, QAR

10/19/94
Date

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CORRECTIVE ACTION RESPONSE FOR CAR #YM-94-099

In response to the YMPQAD determination that corrective actions were unsatisfactory, a detailed review of this CAR was performed. The cited requirement was reexamined to determine appropriate actions relative to the perceived adverse conditions.

Numbered items in the response correspond to the adverse conditions described in Block 6 of this CAR.

A. REMEDIAL ACTIONS

- (1) An addendum to the Scientific Notebook entitled 'WA-0071 Rock Mass Quality Index Derived from NRG Core Data' will be added. The addendum will document the methodology for the calculation of the parameter Jc. No changes to the method or results of the calculations were made. There appears to be no adverse impact to the quality of the data obtained under this SN and with the additional documentation for the Jc methodology, no conditions adverse to quality currently exist. Dave Kessel is responsible for remedial corrective action.
- (2) Additional documentation will be added to the Scientific Notebook entitled 'WA-116 Alcove Blast Project' in sections 4 and 6. Missing titles, column headings, data units, acronyms, and sufficient description of methodology will be added.
John Pott is responsible for remedial corrective action.
- (3) On the first use of Test Control parameters delta and zero, the terms will be defined by annotating these definitions in the subject scientific notebooks.

All remedial corrective actions will be complete by December 16, 1994.

12/15/94

LTR. SHEPHARD TO SPENCE

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B. EXTENT OF THE DEFICIENCY

(1) & (2)

An independent technical review of SNs in place for WAs 71 and 116 will be performed to assess the implementation of the areas identified as deficient in this CAR, specifically:

- Are methodologies for processes used in determining SN data and information adequately defined?
- Is test documentation adequately defined, including titles of name, column headings, data units, and acronyms?
- Are test control parameters adequately defined?

If the deficiencies referenced in this CAR are determined to have a larger number of occurrences, then the scope of technical review will be detailed in a new SNL CAR to cover a comprehensive review of Scientific Notebooks.

David Kessel (Adverse Condition #1) and John Pott (Adverse Condition #2) are responsible for investigative corrective actions.

All the investigative corrective actions described above are scheduled to be completed by December 16, 1994.

(Also see D. below for broader investigative actions.)

- (3)** The parameter, delta and zero, are common to every data acquisition set-up file in this series of experiments. There is a general reference to the SAND document (SAND93-0256, entitled '*Event Triggered Data Acquisition in the Rock Mechanics Laboratory*') that describes the data acquisition software in the front of the cited scientific notebook. This SAND Report defines all common parameters in the set-up files. Therefore, it was determined that no additional investigation is necessary.

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C. ROOT CAUSE DETERMINATION

After thoughtful and meaningful consideration of the subject deficiency, it was determined that the level of detail provided in some SNs and the degree of independent technical review for these SNs were insufficient. In the case of the SN for WA-116 inexperience in performing SN reviews may be a factor. For WA-071 SN the technical review was not performed with the expected level of detail necessary to identify areas where investigation traceability and repeatability might be questionable.

D. CORRECTIVE ACTION TO PRECLUDE RECURRENCE

(1) & (2)

A review will be conducted of all areas of scientific investigation. The review will focus on the various methods used by SNL YMP staff to record their investigations in SN's, as well as the subsequent reviews of the SN's.


Management direction will be provided defining the preferred methods for documenting, verifying, maintaining, and reviewing information in SNs. If necessary, management will have an independent technical reviewer checklist developed.

Based on the investigative results, management will, if necessary, initiate comprehensive training for all SNL YMP staff using scientific notebooks.

Peter Davies and Jim Voigt are responsible for corrective actions to preclude recurrence.

All corrective actions to preclude recurrence are scheduled to be complete by February 20, 1994.

(3) None required.



L.E. Shephard

DEC 15 1994